III. Remarks

A. Status of the claims

Claims 7, 12, 13, 18, 21-36 are pending. Claim 13 has been cancelled by this amendment. Claims 1-6, 8-11, 14-17, and 19-20 were previously cancelled. Claims 7, 12, and 18 have been amended without prejudice. New claims 21-31 have been added. Support for the amendments to the claims and support for the new claims can be found throughout the original specification as filed. It is respectfully submitted that no new matter has been added by virtue of the present amendment.

B. Claim of priority

Applicants have amended the specification to remove the incorporation by reference language previously added with the claim to priority in the Amendment of October 11, 2001, as in accordance with § 201.11 of the Manual of Patent Examining Procedure, the incorporation by reference was not proper. See Manuel of Patent Examining Procedure, Eight Edition, Revision 2, § 201.11, pg. 200-64. It is respectfully submitted that the claims as amended are entitled to the September 4, 1997 priority date.

C. Revocation and Appointment of New Power of Attorney

Included herewith is a Revocation of Power of Attorney with New Power of Attorney and Change of Address of Correspondence Address appointing the following firm:

Davidson, Davidson & Kappel, LLC
485 Seventh Avenue
14th Floor
New York, NY 10018
Telephone: 212-736-1940

Also included with the Revocation of Power of Attorney is the Statement Under 37 CFR 3.73(b) and documents indicating the chain of title.

D. Allowable Subject Matter Withdrawn

In the Office Action, the Examiner stated that "[c]laim 7, 12-13 and 18 have been amended to recite a species of invention previously rejected and not indicated as allowable, therefore, Applicant's pending claims are no longer allowable and the submitted amendment necessitating new grounds of rejection over claims previously indicated as containing allowable subject matter."

The Examiner further stated that "the previously indicated allowable subject matter would have been submitted in independent form, with the rejected subject matter deleted, but suppositories that comprise ***polyethylene glycol***, for which prior art rejections had been made of record, were incorporated into claims 7, 12-13 and 18, thus necessitating new grounds of rejection." (Emphasis added)

In response, the claims have been amended without prejudice to include both polyethylene glycol and polysorbate in the suppository base.

E. 35 U.S.C. §112, first paragraph

Applicants acknowledge with appreciation the Examiner's withdraw of the enablement rejection under 35 U.S.C. §112, first paragraph.

F. Rejections Maintained

1. Beck et al. in view of Singh

In the Office Action, the Examiner maintained the rejection of claims 7, 12-13 and 18 "as previously applied to claims 1-6, 10-11 and 17 (suppository compositions of polyethylene glycol and an antigen) under 35 U.S.C. 103(a) as being unpatentable over Beck et al. (US Pat. 4,756,907) in view of Singh (US Pat. 5,858,371) for reasons of record in paper number 3, paragraph 15 and paper number 20, p 8 and 14-17.

This rejection is traversed. It is respectfully submitted that Beck et al. is directed to "[a]ntibody or antigen containing microparticles for active or passive immunization of the internal female reproductive organs . . . said microparticles capable of being transported after deposition in the vagina by the natural transport mechanism of the internal female reproductive organs across the cervix into the uterus." See Abstract of Beck et al.

It is respectfully submitted that Singh et al. is directed to a composition and method for "treating anorectal diseases including hemorrhoids and colonic diseases with long term effectiveness . . . ." See Abstract of Singh et al.

Independent claims 7 and 12 of the present application are directed to suppository based delivery systems comprising a suppository base comprising polyethylene glycol and polysorbate, and which are adapted for insertion into the urogenital orifice as recited in claim 7 (or vagina as recited in claim 12).

Independent claim 18 of the present application is directed to a method for producing an immune response in humans by inserting a suppository into a urogential orifice of a human, wherein said suppository base of said suppository comprises polyethylene glycol and polysorbate.

It is respectfully submitted that Beck et al. fails to teach or suggest the inclusion of polyethylene glycol and polysorbate combinations in the suppository as recited in claims 7, 12, and 18. Further, as present claims 7, 12, and 18 are directed to urogenital (or vaginal) delivery, it is respectfully submitted that one of ordinary skill in the art would not be motivated to combine Beck et al. which is directed to the vaginal delivery of the formulations described therein with Singh et al. which is directed to the treatment of anorectal diseases with the formulations described therein.

Therefore, as there is no motivation to combine the Beck et al. with Singh et al, the Examiner is respectfully requested to remove this rejection.

2. Beck et al. in view of Azria

Claim 18 was rejected, as previously applied to claims 17 and under 35 U.S.C. 103(a) "as being unpatentable over Beck et al. (U.S. Pat. 4,756,907) in view of Azria (US Pat. [5,149,537]) for reasons or record in paper number 3, paragraph 16 and paper number 20, paragraphs 9 and 18-21."

This rejection is traversed. As noted above, Beck et al. fails to teach or suggest the inclusion of a polyethylene glycol and polysorbate combination in the suppository as recited in claims 18. It is respectfully submitted that Azria is directed to "[s]uppositories comprising a suppository base, a calcitonin and taurocholic acid or a pharmaceutically acceptable salt thereof [that] exhibit improved bioavailability and are well tolerated." See Abstract of Azria. Azria fails to teach or suggest the use of the suppositories described therein in combination with a vaccine or vaccine adjuvant as recited in claim 18.

It is respectfully submitted that one of ordinary skill in the art would not be motivated to combine Beck et al which describes an antibody or antigen containing microparticles with Azria which is directed to suppositories including calcitonin and taurocholic acid.

Further, even assuming arguendo that one were to combine Beck et al. with Azria, it is respectfully submitted that one would not be motivated to include polysorbate in the suppository as Azria describes that "Rabbit studies show that the suppositories of [Azria] have unexpectedly good bioavailability, e.g., compared to **polysorbate 80** and other cholic acid derivatives as enhancer." (emphasis added) See column 3, lines 32-35. In further support of the lack of motivation to include polysorbate in the suppository, Azria notes that "[t]he bioavailability in [the test of Example 4] is indicated to be significantly greater than that obtained with e.g., sodium glycocholate or polyoxyethylene cetyl ether and **polysorbate 80** as an enhancer." (emphasis added) See column 6, lines 5-8.

Therefore, in view of the above remarks, the Examiner is respectfully requested to remove this rejection.

3. Beck et al. in view of Mizuno et al.

Claim 18 was rejected, as previously applied to claims 17, 19, and 20 under 35 U.S.C. 103(a) "as being unpatentable over Beck et al. (US Pat. 4,756,907) in view of Mizuno (US Pat. 4,462,984) for reasons of record in paper number 3, paragraph 17 and paper number 20, paragraphs 10 and 22-23.

This rejection is traversed. It is respectfully submitted that Mizuno et al. is directed to a suppository base composition having "a compatibility with both of a polar drug component and a non-polar drug component." See Abstract of Mizuno et al. The drugs mentioned in Mizuno et al. are those in Table 3 of Mizuno, e.g., indomethacin, acetylsalicylic acid, and ergosterol. It is respectfully submitted that Mizuno fails in the very least to describe compatibility with a vaccine or vaccine adjuvant as recited in claim 18.

Again the above discussion with respect to Beck is also applicable with respect to this rejection. Further, it is respectfully submitted that one of ordinary skill in the art would not be motivated to combine Beck et al which describes an antibody or antigen containing microparticles with Mizuno et al. which is directed to suppositories having a compatibility with both of a polar drug component and a non-polar drug component, and which fails to describe any vaccine or vaccine adjuvant.

Further, in Example 2, Mizuno et al. describe melting the mixture of drug component and suppository base composition. See Column 5, lines 62-66. However, Beck et al. describe molding microcapsules of the active described therein into a solid vaginal suppository by using an appropriate suspension medium such as gelatin (Col. 15, lines 59-61) or inserting microparticles of the active described therein into a preformed gelatin shell and the margin of the shell is then moistened with water and the upper half of the shell is joined to the lower half to complete formation of the suppository. Column

16, lines 7-12. Therefore, it is respectfully submitted that one of ordinary skill in the art would not be motivated to melt the active agent microcapsules or microparticles of Beck et al. with the base composition of Mizuno et al. as Beck et al. describes molding microcapsules of the active described therein into a solid vaginal suppository by using an appropriate suspension medium such as gelatin or inserting microparticles of the active described therein into a preformed gelatin shell.

Therefore, in view of the above remarks, the Examiner is respectfully requested to remove this rejection

4. Brown et al.

Claims 7, 12, and 13 were rejected under 35 U.S.C. 102(b) "as being anticipated by Brown et al. (US Pat. 5,783,194) as evidenced by US 20020034498, for reasons of record in paper number 20, paragraph 24."

This rejection is traversed. It is respectfully submitted that Brown et al fail in the very least to teach the suppository based delivery system of claims 7 and 12. It is respectfully submitted that Brown et al. fail in the very least to teach inclusion of polyethylene glycol and polysorbate combinations in the suppository as recited in claims 7 and 12.

In view of the above remarks, the Examiner is respectfully requested to remove this rejection.

5. Rovinski et al.

Claims 7, 12, and 13 were rejected under 35 U.S.C. 102(b) "as being anticipated by Rovinski et al. (WO98/44788) as evidenced by US 20020034498, for reasons of record in paper number 20, paragraph 25."

This rejection is traversed. Initially, it is noted that that WO98/44788 is not to Rovinski et al., but to Chang. It is respectfully submitted that Chang (WO 98/44788)

fails to teach the suppository based delivery system of claims 7 and 12. It is respectfully submitted that Chang fails in the very least to teach inclusion of polyethylene glycol and polysorbate combinations in the suppository as recited in claims 7 and 12.

In view of the above remarks, the Examiner is respectfully requested to remove this rejection. Should the Examiner's rejection be over a reference to Rovinski et al. rather than Chang which was provided, Applicants respectfully request that the Examiner provide the Applicants with the publication number for the Rovinski et al reference.

6. Lingwood

Claims 7, 12, and 13 were rejected under 35 U.S.C. 102(b) "as being anticipated by Lingwood (US Pat. 6,218,147) as evidenced by US 20020034498, for reasons of record in paper number 20, paragraph 26."

This rejection is traversed. It is respectfully submitted that Lingwood fails to teach the suppository based delivery system of claims 7 and 12. It is respectfully submitted that Lingwood fails in the very least to teach inclusion of polyethylene glycol and polysorbate combinations in the suppository as recited in claims 7 and 12.

In view of the above remarks, the Examiner is respectfully requested to remove this rejection.

7. Melman

Claims 7, 12, and 13 were rejected under 35 U.S.C. 102(b) "as being anticipated by Melman (US Pat. 5,853,767) as evidenced by either Kondo (US Pat. 4,221,705) or Konishi et al (US Pat. 4,360,593), for reasons of record in paper number 20, paragraph 27."

This rejection is traversed. It is respectfully submitted that Melman fails to teach the suppository based delivery system of claims 7 and 12. It is respectfully submitted that Melman fails in the very least to teach a suppository including a vaccine or vaccine

adjuvant(s) of microbial pathogens capable of producing humoral- or cellular-mediated immunity in humans as recited in claims 7 and 12.

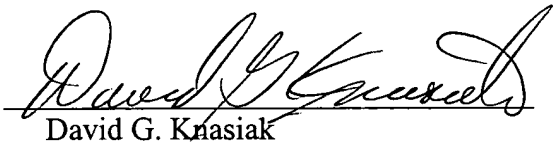
In view of the above remarks, the Examiner is respectfully requested to remove this rejection.

III. CONCLUSION

It is now believed that the above-referenced rejections have been obviated and it is respectfully requested that the rejections be withdrawn. It is believed that all claims are now in condition for allowance.

An early and favorable action on the merits is earnestly solicited. The Examiner is invited to contact the undersigned at the telephone number provided below if he believes that a telephonic interview will advance the prosecution of this application.

Respectfully submitted,
DAVIDSON, DAVIDSON & KAPPEL, LLC

By: 
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